Image A-Fl-1636 $

BEFORE THE BOARD OF APPEALS AND INTERFERENCES
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Rothe et al.	Group Art Unit: 1636
Serial No. 09/689,366	Examiner: Leffers, G.
Filed: October 12, 2000	Attorney Docket No. T95-005-2
For: *Inhibitors of Apoptosis*	CERTIFICATE OF MAILING I hereby certify that this corr. is being deposited with the US Postal Service as First Class Mail in an envelope addressed to the Comm. for Patents, PO Box 1450, Alexandria, VA 22313-1450 on December 12, 2003. Signed _____ Richard Osman

BRIEF ON APPEAL

The Honorable Board of Appeals and Interferences
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Honorable Board:

This is an appeal from the October 23, 2003 final rejection of claims 17-18.

REAL PARTY IN INTEREST

The real party in interest is Tularik Inc., the assignee of this patent application.

RELATED APPEALS AND INTERFERENCES

Appellants are unaware of any related appeals or interferences.

STATUS OF THE CLAIMS

At time of Final Rejection, claims 17-28 were pending, claims 20, 21, 23, 24, 26 and 27 were withdrawn from consideration, claim 19 was allowed and claims 17, 18, 22 and 28 were rejected. Applicant's amendment of 11/24/03 canceled claims 23-28, and the Advisory Action of

12/9/03 withdrew the rejection of claim 22. Hence, claims 19 and 22 are allowed, claims 20 and 21 are withdrawn from consideration, and claims 17 and 18 stand rejected and are subject to this appeal.

STATUS OF THE AMENDMENTS

All Amendments are believed to be properly before the Board.

SUMMARY OF THE INVENTION

Cellular apoptosis, or programmed cell death, may be initiated by a variety of different stimuli including viral infection, certain cell-culture conditions, cell-cell signaling, cytokines, etc. Components of the signal transduction pathways leading to apoptosis provide valuable targets for automated, cost-effective, high throughput drug screening, and have application in domestic and international pharmaceutical and biotechnology drug development programs. Specification, p.1, lines 7-16.

The invention discloses novel human cellular inhibitor of apoptosis proteins (c-IAP1/2; SEQ ID NO: 2 and 4). The native proteins comprise three baculovirus inhibitor of apoptosis repeat (BIR) motifs and a C-terminal RING finger motif. Specification, p.11, lines 11-26.

Deletion mutagenesis of c-IAP1/2 indicated that the N-terminal half of the proteins containing the three BIR motifs (recited as SEQ ID NOS:5/6, 7/8, and 9/10) is sufficient for interaction with TRAF1 and TRAF2. Similarly, combinations of two of the three BIR motifs (e.g. SEQ ID NOS:5 and 7 of c-IAP1, or SEQ ID NOS:6 and 8 of c-IAP2), separated by c-IAP derived intervening sequences of varying lengths are assayed for TRAF1 and TRAF2 binding. This indicates that BIR motifs represent a novel protein:protein interaction domain. The RING finger domain of c-IAP1/2 (SEQ ID NOS:11/12) is not required for interaction with TRAFs, but rather mediates subsequent steps in the c-IAP1/2 signaling cascade. Specification, p.12, lines 7-16; SEQ ID NO correspondence is at Specification, p.14, lines 24-30.

The subject claim 17 is directed to a protein comprising a human c-IAP BIR motif comprising SEQ ID NO:9, wherein the BIR motif provides a protein:protein interaction domain which binds a TRAF1/2 protein of the apoptotic pathway. Pending claim 17.

The subject claim 18 is directed to a protein comprising at least two of three c-IAP BIR domains: a first domain comprising SEQ ID NO: 5 or 6, a second domain comprising SEQ ID NO: 7 or 8, and a third domain comprising SEQ ID NO: 9 or 10, wherein the protein binds a TRAF1/2 protein of the apoptotic pathway. Pending claim 18.

ISSUE

I. WHETHER CLAIMS 17-18 ARE PATENTABLE UNDER 35USC112, FIRST PARAGRAPH (WRITTEN DESCRIPTION).

GROUPING OF THE CLAIMS

For Issue I, claims 17 and 18 stand separately.

ARGUMENT

I. CLAIMS 17-18 ARE PATENTABLE UNDER 35USC112, FIRST PARAGRAPH (WRITTEN DESCRIPTION)

The only statute relied upon for the pending rejections is the written description requirement of 35USC112, first paragraph. The written description requirement does not require the applicant to describe exactly the subject matter claimed, instead the description must clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed (Moba B.V. v. Diamond Automation Inc., 66 USPQ2d 1429, CA FC 2003).

The pending claims consist of protein claims 17, 18 and 19, and corresponding method claims 20-22. Claim 19 is allowed; hence, the rejection relies on distinguishing claims 17 and 18 from claim 19 with respect to the written description.

Claim 17 recites an isolated protein comprising a c-IAP BIR motif comprising SEQ ID NO:9, wherein the BIR motif provides a protein:protein interaction domain which binds TRAF1/2. Claim 18 recites an isolated protein comprising two of the following three cIAP BIR domains: a first domain comprising SEQ ID NO: 5 or 6, a second domain comprising SEQ ID NO: 7 or 8, and a third domain comprising SEQ ID NO: 9 or 10, wherein the protein binds TRAF1/2. Claim 19 recites an isolated human c-IAP comprising SEQ ID NO:2. All three

claims recite a protein "comprising" a specified sequence; hence, all three claims are open to arbitrary additional components or residues, so long as the requisite amino acid sequence is present.

Claim 17 requires a protein comprising SEQ ID NO:9. This sequence defines a novel third cIAP "BIR domain", defined by residues 287-334 of SEQ ID NO:2, which sequence is separately disclosed as SEQ ID NO:9. The claim expressly requires that the recited domain provides a protein:protein interaction domain which binds a TRAF1 or TRAF2.

The Specification expressly informs that the invention includes deletion mutants of cIAP (SEQ ID NO:2) which have a disclosed cIAP specific activity (p.3, lines 4-7). The Specification informs that the cIAP BIR domains (e.g. SEQ ID NO:9) represent novel protein:protein interaction domains (Specification, p.12, lines 13-14). The Specification teaches how multiple BIR domains can be mixed-and-matched in functional recombinant chimeras (e.g. Specification, p.12, lines 10-14). The Specification shows in experimental detail how to screen for interactions of such BIR domain containing proteins with proteins like TRAF1 and TRAF2 (e.g. Specification, p.11, line 27 - p.14, line 13). Accordingly, the Specification conveys both possession and use of proteins comprising the specifically recited cIAP BIR domain.

The Action's discussion of protein structure and function is not on point, and inapt is the Action's resort to drama and obfuscation: discerning and even practicing the invention does not require invoking Holy Grails or legendary knights of King Arthur; the invention does not relate to some hypothetical 3rd cIAP protein, nor does the invention require determining three dimensional molecular structures of anything. The present invention and relevant issues are much more mundane. A novel protein interaction domain is disclosed. The ability to recombine this domain into functional chimeric proteins is disclosed. And the claims are properly limited to a protein specifically comprising the novel interaction domain.

Claim 18 requires two of the following three cIAP BIR domains: a first domain comprising SEQ ID NO: 5 or 6, a second domain comprising SEQ ID NO: 7 or 8, and a third domain comprising SEQ ID NO: 9 or 10, wherein the protein binds human TRAF1 or TRAF2.

The Specification expressly informs that the invention includes deletion mutants of cIAP (SEQ ID NO:2) which have a disclosed cIAP specific activity (p.3, lines 4-7). The Specification

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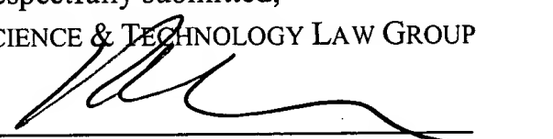
Appellants respectfully request reversal of the pending Final Action by the Board of Appeals.

We petition for and authorize charging our Deposit Account No.19-0750 all necessary extensions of time. The Commissioner is authorized to charge any fees or credit any overcharges relating to this communication to our Dep. Acct. No.19-0750 (order T95-005-2).

Respectfully submitted,
SCIENCE & TECHNOLOGY LAW GROUP



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Mission Statement, USPTO External Customer Services Guide

CLAIMS ON APPEAL

17. An isolated protein comprising a human cellular inhibitor of apoptosis protein (c-IAP) baculovirus inhibitor of apoptosis repeat (BIR) motif comprising SEQ ID NO:9, wherein the BIR motif provides a protein:protein interaction domain which binds at least one of a human tumor necrosis factor receptor associated factor 1 (TRAF1) and a human tumor necrosis factor receptor associated factor 2 (TRAF2).

18. An isolated protein comprising at least two of the following three domains: a first domain comprising SEQ ID NO: 5 or 6, a second domain comprising SEQ ID NO: 7 or 8, and a third domain comprising SEQ ID NO: 9 or 10, wherein the protein binds at least one of a human tumor necrosis factor receptor associated factor 1 (TRAF1) and a human tumor necrosis factor receptor associated factor 2 (TRAF2).

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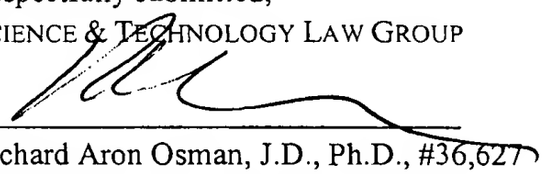

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